

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO**

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JEANETTE PEREZ MACEIRA,  
JOSE LUIS MATEO PEREZ,  
LILLIAM M. ORTIZ,  
DANISHA M. ORTIZ SANTIAGO,  
YAMEL SANTIAGO RIVERA,  
ELBA MELENDEZ FIGUEROA,  
LIANIBEL COLON SANCHEZ,  
IRIS M. RIVERA VARGAS,  
IDALIA VARGAS GRATACOS, and  
JUANA CASTRO MORENO, individually and on  
behalf of all others similarly situated,

Case No. 3:23-cv-01445-CVR

Plaintiffs,

v.

BALCHEM CORP.,  
CUSTOMED, INC.,  
MEDTRONIC PR, INC.,  
EDWARD LIFESCIENCES TECHNOLOGY SARL,  
STERI-TECH, INC., and  
MAYS CHEMICAL COMPANY OF PUERTO RICO,  
INC.,

Defendants.

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**PLAINTIFFS' CORRECTED FIRST AMENDED CLASS ACTION COMPLAINT  
AND DEMAND FOR A JURY TRIAL**

## **NATURE OF THE ACTION**

Ethylene Oxide (“EtO”), a globally recognized human carcinogen for decades, has been silently permeating in the air of certain American communities, primarily being emitted from medical sterilization sites and chemical plants producing everyday items like antifreeze. This insidious chemical, officially deemed cancer-causing by authorities like the Environmental Protection Agency (“EPA”), National Toxicology Program, and the International Association of Research on Cancer, is alarmingly prevalent in the air in many communities in Puerto Rico, where the toxin is continuously released from sterilization facilities and impacts approximately 13% of the island's population, including tens of thousands of children.<sup>1</sup> Recent investigations reveal a disturbing pattern: communities suffering the most from exposure to toxic EtO emissions in America are at or below the federal poverty line. These communities, already vulnerable, bear the brunt of the health hazards from a pollutant they have little to no role in producing and are often kept in the dark about the greatest health threat lurking in their air.

Health implications of continuous EtO exposure are dire and far-reaching, encompassing a range of cancers—including breast, blood, stomach, leukemia, lymphoma, pancreatic, and brain, as well as reproductive problems and miscarriages. For children, who are more vulnerable to the impacts of EtO, the stakes are even higher, with EtO exposure increasing the risk of severe DNA mutations. Even short-term exposure to this toxin can initiate a slew of symptoms like respiratory issues, nausea, headaches, fatigue, and neurological disorders. Plaintiffs seek injury compensation as well as medical monitoring costs for being affected by EtO exposure within a four-mile radius of PR Sterilization Facilities from the date of first EtO exposure.

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<sup>1</sup> Union of Concerned Scientists, *Ethylene Oxide in Puerto Rico*, UNION OF CONCERNED SCIENTISTS (February 7, 2023), <https://www.ucsusa.org/resources/puerto-rico>, (last accessed: February 9, 2024).

This class action lawsuit is a direct response to the harm and suffering endured by the plaintiffs, traced back to the negligent handling of EtO by the PR Sterilization Facilities—Customed, Inc., Medtronic PR, Inc., Edward LifeSciences Technology Sarl, and Steri-Tech, Inc. (“Sterilizer Defendants”—along with their EtO distributor, Mays Chemical Company of Puerto Rico, Inc., and their EtO manufacturer, Balchem Corp. Through their reckless practices and by acting in concert, Defendants have unleashed a deadly and ever-present series of plumes of EtO across the island for decades, poisoning the air in four Puerto Rican communities and causing marginalized communities, once again, to suffer disproportionately from environmental contamination in Puerto Rico, just as in mainland America.

Of particular concern, and one of the fundamental reasons for the herein requested medical monitoring class, is the high likelihood of latent disease developing decades from now for the people—particularly children—who are inescapably exposed to this deadly toxin daily due to Defendants’ actions and omissions. Thankfully, unlike less fortunate generations of the past, we have the capacity with modern healthcare to regularly scan for, monitor, and track disease progression—preventing readily avoidable deaths through early detection and treatment. The ongoing EtO contamination crisis in Puerto Rico necessitates this modern solution in the interests of the fair administration of justice and to meet the coequal goals of damages consistent with the common law tradition—to compensate and deter. Anything less would succumb the state of public health in these communities to this fate: many thousands of Puerto Ricans, including children, will die readily avoidable deaths from diseases that could have been detected earlier and treated safely—diseases that were caused by EtO emissions resulting from these Defendants.

## **INTRODUCTION**

1. EtO was first listed in the *Fourth Annual Report on Carcinogens* in 1985 as reasonably anticipated to be a human carcinogen based on limited evidence of carcinogenicity from studies in humans and sufficient evidence of carcinogenicity from studies in experimental animals. The listing was revised to “*known to be a human carcinogen*” in the *Ninth Report on Carcinogens* in 2000.<sup>2</sup>

2. Despite these ultrahazardous dangers, Defendants disregarded EtO’s harmful properties as an environmental toxin, resulting in dangerous volumes of EtO being released into the surrounding communities.

3. For decades, Sterilizer Defendants have been emitting substantial quantities of EtO into the air supply of a sizeable population in Puerto Rico. As a result, those who live, work, pray, and attend school in the surrounding area of these facilities have unknowingly been inhaling EtO in the air they breathe on a routine basis.<sup>3</sup>

4. Defendants never informed the residents of these Puerto Rican communities or those who attend school, live, pray, or work nearby that they systematically emit EtO into the air, nor did Defendants warn them that these residents routinely and continuously breathe in a known human carcinogen.

5. Through their industrial processes, Defendants work in concert to emit EtO into the air, allowing it to be carried by the wind and natural air movement throughout the area surrounding

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<sup>2</sup> National Toxicology Program, Department of Health and Human Services, Fifteenth Edition. “EtO. “Page 1, <https://ntp.niehs.nih.gov/sites/default/files/ntp/roc/content/profiles/ethyleneoxide.pdf>.

<sup>3</sup> United States Environmental Protection Agency, *Hazardous Air Pollutants: Ethylene Oxide, Salinas, Puerto Rico (Steri-Tech, Inc.)*, <https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/forms/salinas-puerto-rico-steri-tech-inc>, (last accessed: February 9, 2024); See also Attached Maps of sites.

the PR Sterilization Facilities. As such, residents in the area have unknowingly been exposed to carcinogenic EtO for decades—some at levels 600 times the national average cancer risk.

6. At all relevant times, the Defendants knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and causes various illnesses. There is no known safe level of EtO exposure; its carcinogenic and DNA-damaging effects have been widely studied and known since the 1940s and definitively known to Defendants since at least 1985. Notwithstanding, Defendants chose to operate their business in a way such that EtO is emitted in a densely populated area full of children, houses, parks, schools, and businesses.

7. On February 7, 2023, the Union of Concerned Scientists published an intensive report (“USC report”) on the exposure of EtO to communities in Puerto Rico.

8. The Union of Concerned Scientists found that the maximum cancer risk levels from facility specific EtO emissions range from 800 to 6,000 cases per 1 million people, all of the PR Sterilization Facilities are located within five miles of more than 413,000 Puerto Ricans (which constitute 13 percent of the population), and nearly 300 schools and childcare centers.

### **THE PARTIES**

9. Plaintiff Jeanette Perez Maceira is a natural person and a citizen of the Commonwealth of Puerto Rico.

10. Plaintiff Jose Luis Mateo Perez is a natural person and a citizen of the Commonwealth of Puerto Rico.

11. Plaintiff Lilliam M. Ortiz is a natural person and is a citizen of the State of Florida.

12. Plaintiff Danisha M. Ortiz Santiago is a natural person and a citizen of the Commonwealth of Pennsylvania.

13. Plaintiff Yamel Santiago Rivera is a natural person and a citizen of the Commonwealth of Pennsylvania.

14. Plaintiff Elba Melendez Figueroa is a natural person and a citizen of the State of Florida.

15. Plaintiff Lianibel Colon Sanchez is a natural person and a citizen of Miami, Florida.

16. Plaintiff Iris M. Rivera Vargas is a natural person and a citizen of the Commonwealth of Puerto Rico.

17. Plaintiff Idalia Vargas Gratacos is a natural person and a citizen of Villalba, Puerto Rico.

18. Plaintiff Juana Castro Moreno is a natural person and a citizen of the Commonwealth of Puerto Rico.

19. Defendant Balchem Corp. is a corporation organized and existing under the laws of Maryland with its principal place of business located at 5 Paragon Drive, Montvale, New Jersey.

20. Defendant Customed, Inc is a domestic corporation organized and existing under the laws of Puerto Rico with its principal place of business located at Igualdad Street Final #7, Fajardo, Puerto Rico.

21. Defendant Medtronic Puerto Rico Operations, Co., also known as Medtronic PR, Inc. is a corporation organized and existing under the laws of the Cayman Islands with its principal place of business located at Rd 909 Km 0.4 Mariana Humacao, PR, 00791, United States, which operates a facility located at PR-149 KM 56.3 Villalba, Puerto Rico.

22. Defendant Edward LifeSciences Technology Sarl is a corporation organized and existing under the laws of Switzerland with its principal place of business located at Route de l'Etraz 70 Nyon, 1260, Switzerland, which operates a facility located at State Road 402 North, Km 1.4 Industrial Park Añasco 00610-1577, Puerto Rico.

23. Defendant Steri-Tech, Inc. is a corporation organized and existing under the laws of the Commonwealth of Puerto Rico with its principal place of business located at Parque Industrial, Salinas, Puerto Rico.

24. Defendant Mays Chemical Company of Puerto Rico, Inc., also doing business as Mays Ochoa, is a corporation organized and existing under the laws of the Commonwealth of Puerto Rico with its principal place of business located at Calle 2, Industrial Zone in the Barrio Palmas, Cataño, 00962, Puerto Rico. It also has a warehouse in Turabo Industrial Park and one in Gurabo, Puerto Rico.

25. Defendants Customed, Inc., Medtronic PR, Inc., Edward LifeSciences Technology Sarl and Steri-Tech, Inc., operate medical sterilization facilities in Puerto Rico using EtO manufactured by Balchem Corp. and distributed by Mays Chemical Company of Puerto Rico, Inc.

#### **JURISDICTION AND VENUE**

26. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2), because (i) at least one member of the Class is a citizen of a different state than Defendants, (ii) the amount in controversy exceeds \$5,000,000, exclusive of interests and costs, and (iii) none of the exceptions under that subsection apply to this action.

27. This Court has personal jurisdiction over Defendants because they operate or previously operated industrial facilities in this District, currently conduct or previously conducted business throughout this District, and committed tortious acts within this District that are the subject of this suit.

28. Venue is proper pursuant to 28 U.S.C. § 1391(b) because a substantial part of the events or omissions giving rise to the claims of Plaintiffs and the Class occurred in this District.

### **COMMON FACTUAL ALLEGATIONS**

29. Plaintiffs have each resided, worked, or attended school within approximately four miles or less from the Sterilizer Defendants' facilities in the Commonwealth of Puerto Rico for a significant amount of time while Sterilizer Defendants were emitting unsafe and hazardous levels of EtO into the air.

30. Toxic chemicals and fumes released by Sterilizer Defendants were ongoing upon Plaintiffs' properties and persons throughout the duration of Plaintiffs' residence at Plaintiffs' properties.

31. At the time of the purchase or lease of Plaintiffs' properties, and/or the time that Plaintiffs attended work or school, Plaintiffs were unaware that they were being subjected to dangerous levels of EtO, nor could Plaintiffs have known the extent of the EtO emissions coming from the Defendants' facilities.

32. EtO is an odorless and colorless flammable gas at room temperature that is produced in large volumes for industrial uses.

33. Commercial / industrial medical-equipment sterilizers use EtO in their sterilization processes.

34. The EtO sterilization process generally begins by placing medical equipment in a gas chamber. After air is pumped out of the chamber, EtO is introduced and allowed to diffuse into the products for several hours. Once the medical equipment is sterilized, the EtO is pumped out of the chamber, and the remaining EtO is supposed to be allowed to slowly dissipate.

35. Through their industrial processes, the Sterilizer Defendants emitted EtO into the air, allowing it to be carried by the wind and natural air movement throughout the area surrounding the facilities. As such, residents' properties in the area have unknowingly been exposed to carcinogenic EtO for decades.

36. EtO is highly reactive, readily taken up by the lungs, efficiently absorbed into the blood stream, and easily distributed throughout the human body.

37. At all relevant times, the Defendants knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and causes various illnesses. There is no known safe level of cumulative EtO exposure; its carcinogenic and DNA-damaging effects have been widely studied and known since the 1940s and definitively known to Defendants since at least 1985. Furthermore, in 2016, the EPA presented new data revealing that the EPA determined EtO increased the risk of cancer 60 times what was previously thought.

38. Notwithstanding, for decades, Defendants chose to operate their businesses such that the supply chain culminates in the emission of EtO in densely populated areas full of children, houses, parks, schools, and businesses, significantly increasing the risk of these Puerto Ricans contracting a serious disease.

39. Further, although technologies to control EtO have been available and widely used since the 1980s, Defendants operated for years in Puerto Rico without using the best practices and control technologies available to reduce their emissions.

40. As sophisticated corporations and long-term users, transporters, and emitters of EtO, Defendants had superior knowledge and access to information regarding the dangers of EtO, more so than the general public or Plaintiffs.

41. While the harmful properties of EtO are not widely known to the average person who is not involved in the business of EtO sterilization, the harmful properties of EtO have been known—or should have been known—to Defendants and anyone in the business of using and emitting EtO as part of a sterilization process, for decades. By way of example:

- a. In a 1977 article, the National Institute of Occupational Safety and Health (“NIOSH”) concluded that occupational exposure to EtO may increase the frequency of genetic

mutations in humans. The NIOSH report also raised concerns about the potential carcinogenicity of EtO.

- b. In 1981, NIOSH released a subsequent report which recommended that EtO be regarded in the workplace as a potential occupational carcinogen. NIOSH based its recommendation on new evidence of EtO's carcinogenic, mutagenic, and reproductive hazards, including studies demonstrating that EtO induced cancer in experimental animals. Specifically, the studies showed an increase in instances of leukemia in line with increases of EtO concentrations, in addition to other adverse effects on reproductive health. An epidemiological investigation of Swedish workers exposed to EtO also revealed increased incidences of leukemia and other cancers.
- c. In 1985, the U.S. Department of Health and Human Services published the Fourth Annual Report on Carcinogens and classified EtO as reasonably anticipated to be a human carcinogen.
- d. In the early 1990s, NIOSH published the largest and most informative epidemiological study of EtO. The study analyzed over 18,000 employees working with EtO at fourteen different industrial facilities sterilizing medical equipment and food spices. The study found sufficient evidence to support a causal link between exposure to EtO and increased mortality from lymphatic and hematopoietic cancers. Follow-up studies have additionally demonstrated an association between EtO exposure and breast cancer.
- e. In 1994, as a result of these findings, the World Health Organization ("WHO") listed EtO as a Group 1 human carcinogen—the agency's highest risk classification—finding EtO to be carcinogenic to humans.
- f. In 2000, following suit, the U.S. Department of Health and Human Services reclassified EtO to "known to be a human carcinogen."

- g. The U.S. Department of Labor’s Occupational Safety and Health Administration’s (hereinafter “OSHA”) 2002 fact sheet on EtO indicates that “[b]oth human and animal studies show that EtO is a carcinogen” and requires employers to provide clear signs and labels notifying workers of EtO’s “carcinogenic and reproductive hazards.”<sup>4</sup>
- h. In 2016, the EPA’s Integrated Risk Information System similarly reclassified EtO as carcinogenic to humans and increased—by a multiple of 30 in adults and 60 in children—its estimate of EtO’s cancer potency.<sup>5</sup>

42. EtO exposure affects the most vulnerable members of the population. The EPA states that “for a single year of exposure to EtO, the cancer risk is greater for children than for adults. That is because EtO can damage DNA.”

43. Despite knowing these risks, Defendants’ EtO sterilization process did not comply with safe and prudent methods of EtO sterilization.

44. At all relevant times, Defendants—by way of failure to implement control measures to limit emissions, failure to upgrade sterilization equipment, intentional shortening of EtO degassing/aeration/quarantining time, and/or other unsafe practices—subjected Plaintiffs and the Puerto Rican communities to unhealthy and dangerous levels of EtO in order to increase profits and/or cut costs.<sup>6</sup>

45. At all relevant times, Defendants failed to train their employees and managers, resulting in unsafe practices which created risky EtO sterilization practices with the goal of saving money.

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<sup>4</sup> See, Occupational Safety and Health Administration (OSHA), *OSHA Fact Sheet: Ethylene Oxide*, [https://www.osha.gov/OshDoc/data\\_General\\_Facts/ethylene-oxide-factsheet.pdf](https://www.osha.gov/OshDoc/data_General_Facts/ethylene-oxide-factsheet.pdf), (last accessed: February 9, 2024).

<sup>5</sup> Max Blau and Lylla Younes, *The Dirty Secret of America’s Clean Dishes*, ProPublica (Dec. 20, 2021) <https://www.propublica.org/article/the-dirty-secret-of-americas-clean-dishes>, (last accessed: February 9, 2024).

<sup>6</sup> See Replacing Ethylene Oxide Document from EPA, Attached.

46. Defendants had knowledge of faulty/ineffective training systems, faulty/ineffective supervision, and employees' unfitness to perform their jobs safely.

47. On August 22, 2018, the U.S. EPA released the 2014 National Air Toxic Assessment ("NATA")—a screening tool that estimates cancer risks based on emission data in 76,727 census tracts across the United States. The 2014 NATA revealed 109 census tracts in the United States with cancer-risk scores greater than 100 cases per one million people exposed to toxic air pollution during their lifetime, more than what the U.S. EPA considers "acceptable" limits.

48. Exposure to EtO has been widely studied, and its negative health effects are well documented. Presently, there is evidence linking exposure to increased risk of lymphohematopoietic cancer such as non-Hodgkin's lymphoma, multiple myeloma, and lymphocytic leukemia; breast cancer; tumors in the lungs, uterus, and the brain; and reproductive and developmental impairments including increased rate of miscarriages and infertility.

49. Commercial medical equipment sterilizers use the EtO sterilization process on over 20 billion healthcare products annually in the United States. The EtO sterilization process begins by placing medical equipment in a gas chamber. After air is pumped out of the chamber, EtO is injected and allowed to diffuse into the products for several hours. Once the medical equipment is sterilized, the EtO is pumped out of the chamber and the remaining EtO is allowed to slowly dissipate. Each time this sterilization cycle is run, EtO is emitted—whether through controlled or uncontrolled emissions known as "fugitive emissions"—into the air and inhaled by the surrounding community.

50. EPA regulations currently do not require fugitive emissions to be reported, so tracked emission figures do not accurately account for these fugitive emissions, which include

untracked ventilation due to lack of maintenance, faulty design, and other untracked escape pathways for this highly explosive air toxin.

51. EtO is extremely flammable and explosive in its room-temperature gaseous form—therefore, it is typically handled and shipped as a refrigerated liquid to mitigate those risks.

52. In fact, EtO is so explosive that it is one of the main components in thermobaric and “fuel-air explosive” weapons used by the US military, sometimes referred to as “vacuum bombs.” These bombs often produce an atomic-mushroom-like smoke signature and blast characteristics that look like “mini-nukes.” They are among the most powerful nonnuclear weapons in our country’s arsenal. EtO is a preferred compound for such military uses because it has a shock wave effectiveness of 5:1 compared to dynamite—in other words, to duplicate the shock wave of 5 pounds of dynamite, you need just 1 pound of EtO.<sup>7</sup>

53. In addition to EtO’s explosive quality, it is also odorless—unless one is to inhale very concentrated amounts, which is effectively only possible in occupational exposure scenarios. Other industries that handle chemicals with these characteristics—such as the liquified petroleum gas industry—combine an additive with their products to alert users and other nearby individuals of leaks. Such measures have proven to be effective in alerting propane users to a problem - and giving them the time they need to ensure their safety. Defendants have instituted no such readily available safety precautions with EtO.

54. In manufacturing, distributing, and using EtO, Defendants have neglected to add any odorous substances to EtO to alert employees and residents in the neighborhoods of the Sterilization Facilities that EtO is endangering them.

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<sup>7</sup> Meyer R, Köhler, J., Homberg A. *Explosives*. 6th ed. Weinheim, Germany: Pg. 142.

55. Balchem Corp. is a global leader in the production and sale of performance gases, including EtO. EtO from Balchem Corp. is distributed in cylinders and drums globally as per the Balchem Corp. website. Page 5 of the August 24, 2022, data sheet available on the website (only in English) presents the following warning:

Statement of Hazards: DANGER! Extremely flammable liquid and gas under pressure. May form explosive mixtures with air. Highly Reactive. Harmful or fatal if inhaled and may cause delayed lung injury, respiratory system and nervous system damage. Inhalation may cause dizziness or drowsiness. Liquid contact may cause frostbite. May cause allergic skin reaction. Harmful if swallowed. May cause adverse blood effects, liver and kidney damage based on animal data. Cancer and reproductive hazard.

HAZARD RATINGS: (0 = minimum; 4 = maximum) HMIS Rating: Health = 3

Flammability = 4

Reactivity = 3

Personal Protection Code = X

56. Furthermore, the fact that this data sheet is only available in English is concerning because Plaintiffs and Class Members predominantly speak Spanish.<sup>8</sup>

57. According to the EPA, Balchem is the only EtO "technical registrant."<sup>9</sup> A technical registrant is a company or individual that owns the source of the active ingredient in a pesticide product and has registered it with the EPA.<sup>10</sup>

58. A technical registrant is responsible for providing the data and information to support the safety and efficacy of the active ingredient, as well as complying with the EPA's regulations and requirements. A technical registrant typically has a significantly greater investment, as well as greater responsibilities and liabilities, than an end-use product registrant.

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<sup>8</sup> Balchem Corporation, *Safety Data Sheet*, [www.balchem.com/performance-gases/wp-content/uploads/sites/5/2021/02/SDS\\_ARC\\_Ethylene-Oxide-1.pdf](http://www.balchem.com/performance-gases/wp-content/uploads/sites/5/2021/02/SDS_ARC_Ethylene-Oxide-1.pdf), (last accessed: February 9, 2024).

<sup>9</sup> United States Environmental Protection Agency (EPA), *Ethylene Oxide Proposed Interim Registration Review Decision Case Number 2275*, (March, 2023) <https://www.epa.gov/system/files/documents/2023-04/eto-pid.pdf>, (last accessed: February 9, 2024).

<sup>10</sup> United States Environmental Protection Agency (EPA), *How to Register a Pesticide – A Guide for Applicants New to the Process*, <https://www.epa.gov/pesticide-registration/how-register-pesticide-guide-applicants-new-process>, (last accessed: February 9, 2024).

59. Further, Balchem Corp. provides training to one or more of the Sterilizer Defendants, namely Medtronic PR, Inc. (which has operated a facility at PR-149 KM 56.3 Villalba, Puerto since 1998) Customed, Inc. (which operates a facility at Igualdad Street, Fajardo, Puerto Rico since 2005), Steri-Tech, Inc. (which operates a facility at RD. 701 KM 0.7, Salinas, Puerto Rico since 1986) and Edwards LifeSciences Technology Sarl (which operates a facility located at 402 KM 1.4 Industrial Park, Anasco, Puerto Rico since 1989.)

60. On July 11, 2023, the Occupational Safety and Health Administration (OSHA) announced it issued a \$393,798 fine to Balchem Corp. subsidiary, BCP Ingredients, Inc. after agency inspectors found dozens of serious safety and health violations at the company's chemical plant.<sup>11</sup>

61. In October of 2021, OSHA cited the same facility for 24 serious safety and health violations, including inadequate medical evaluation procedures for workers exposed to ethylene oxide.<sup>12</sup>

62. Balchem's wholly owned subsidiary BCP Ingredients, Inc. was cited for safety violations which included:

- a. Inadequate process safety management procedures and monitoring;
- b. Failing to develop an emergency evacuation plan;
- c. Failing to train workers on actions to take in the event of a chemical release;
- d. Exposing respirators to ethylene oxide while in storage; and
- e. Allowing electrical safety hazards.<sup>13</sup>

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<sup>11</sup> Guy Burdick, *OSHA Issues A Pair of Six-Figure Fines*, EHS DAILY ADVISOR (July 13, 2023), <https://ehsdailyadvisor.blr.com/2023/07/osha-issues-a-pair-of-six-figure-fines/> (last accessed: February 9, 2024).

<sup>12</sup> U.S. Department of Labor, Occupational Safety and Health Administration, *Citation and Notification of Penalty*, (October 1, 2021), [www.dol.gov/sites/dolgov/files/OPA/newsreleases/2021/10/OSHA%2020211760A.pdf](http://www.dol.gov/sites/dolgov/files/OPA/newsreleases/2021/10/OSHA%2020211760A.pdf) (last accessed: February 9, 2024). (last accessed: February 9, 2024).

<sup>13</sup> *Id.*

63. “Ethylene oxide is a colorless and flammable gas and unsafe exposure can cause cancer and other serious health issues,” Karena Lorek, OSHA’s Kansas City, Missouri, area director, said in an agency statement. “The company’s failure to address its previous violations and follow OSHA regulations is troubling. BCP needs to bring its monitoring procedures into compliance immediately and re-evaluate its engineering processes to make sure its employees are kept safe and healthy.”

64. Balchem Corp. supplies EtO to its Puerto Rico distributor, Mays Ochoa, which distributes EtO to these facilities<sup>14</sup> and is the facilitator of Balchem’s products and safety procedures in Puerto Rico.<sup>15</sup>

65. Unfortunately, these “safety” procedures appear to be rarely followed or enforced at the EtO facilities. For instance, while Balchem provided dedicated training to Steri-Tech employees every two years on practices for handling EtO, employees who were hired in between the two-year gap of Balchem’s training were only provided with printed copies of the presentations used by Balchem training personnel with no additional guidance or explanation before starting work.<sup>16</sup> Likewise, next to no training took place at Medtronic as to the risks of EtO—occupationally or environmentally—and relevant personal protective equipment was not provided.<sup>17</sup>

66. Through their industrial processes and the lack of training from Balchem and Mays Ochoa, and lack of enforcement, these plants emit EtO into the air, poisoning the air in communities surrounding the facilities.

<sup>14</sup> See attached Bill of Lading, by Mays from Balchem to Steri-Tech.

<sup>15</sup> See attached Declaration of Emely Hernandez, ¶¶ 23-27. The full Declaration is incorporated herein by reference, in the interest of judicial economy.

<sup>16</sup> Id. at ¶ 27.

<sup>17</sup> See attached Declaration of Ramon Luis Perez Vargas, ¶¶ 8-11. The full Declaration is incorporated herein by reference, in the interest of judicial economy.

67. As such, local residents, students, and workers in the areas of these facilities have unknowingly been subjected to and breathed in EtO emissions for decades. All the while, PR Sterilization Facilities emitted EtO, Mays Ochoa distributed EtO, and Balchem Corp. manufactured EtO and knew, or should have known, that EtO is dangerous, toxic, carcinogenic, mutagenic, and the cause of various illnesses.

68. Exposure to toxic chemicals may cause latent yet substantial injury, which should be compensated, even if the full effect of the exposure is not immediately apparent.

69. Named Plaintiffs and all Class Members suffered appreciable harm as a result of inhaling air poisoned with Defendants' dangerously high EtO emissions.

70. Medical monitoring is necessary to detect the potential onset of a serious illness or disease due to physiological changes that indicate a substantial increase in risk of harm from exposure to EtO.

71. Therefore, as a result of this harm, it is reasonably necessary for Plaintiffs to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of their EtO exposure.

72. Monitoring procedures exist in the contemporary medical field—specific to EtO exposure—that make possible the early detection of cancer, the disease progression of cancer, and the presence of biomarker abnormalities that indicate the development of cancer.

73. Conversely, when cancer care is delayed or inaccessible there is a lower chance of survival, greater problems associated with treatment, and higher costs of care.

74. Therefore, preventative diagnostic tests for the early detection of signs or symptoms of latent cancers are medically necessary to assure early diagnosis and effective treatment,

mitigating the risk of harm of these serious diseases. In other words, early detection increases the chances of survival.

75. It is inequitable to place the economic burden of such care on the unwittingly exposed plaintiffs/class member rather than on the liable Defendants.

76. Having been harmed by regularly breathing in Defendants' elevated levels of EtO, Plaintiffs and Class Members seek as damages the costs of such diagnostic testing and medical monitoring, in order to detect the early onset of disease. This testing will, in turn, identify the need for treatment, management, and rehabilitation in the event cancer is detected and Plaintiffs and/or any Class Members are diagnosed.

#### **FACTS SPECIFIC TO PLAINTIFFS**

77. Plaintiff Jeannette Perez Maceira is a resident of the La Margarita Community in Salinas, Puerto Rico and has lived at her residence since 1977. After exposure to EtO she was diagnosed with breast cancer in 2016 and received a mastectomy at the Hospital Auxilio Mutuo in San Juan, Puerto Rico.

78. Plaintiff Jose Luis Mateo Perez is a resident of the La Margarita Community in Salinas, Puerto Rico and has lived there since 1980. After exposure to EtO he suffers from asthma.

79. Plaintiff Lilliam M. Ortiz was a resident of the La Margarita Community in Salinas, Puerto Rico from 1982-2007 and was diagnosed with thyroid cancer in 2022.

80. Plaintiff Danisha M. Ortiz Santiago is a resident of Allentown, Pennsylvania. Danisha lived at her grandparents' house in the La Margarita Community in Salinas Puerto Rico from 1994 - 2003. After exposure to EtO in utero, she was diagnosed with Spina Bifida on April 29, 1994.

81. Plaintiff Yamel Santiago Rivera is a resident of Allentown, Pennsylvania. Yamel lived at her parent's house in Salinas, Puerto Rico from 1967 - 2002. After exposure to EtO, she was diagnosed with Thyroid issues in 1976 and Arthritis 2021.

82. Plaintiff Elba Melendez Figueroa is a resident of Tampa, Florida. Elba lived in Salinas, Puerto Rico from 1977 until 2019. She had to move to Tampa after being exposed to EtO and being subsequently diagnosed with maxillary sinus cancer on May 26, 2015 at the *Colegio de Cirujanos Dentistas de Puerto Rico*.

83. Plaintiff Lianibel Colon Sanchez is a resident of Miami, Florida. Lianibel lived in Salinas, Puerto Rico from 1999 until 2017. After exposure to EtO, she was diagnosed with Asthma in 2021.

84. Plaintiff Iris M. Rivera Vargas is a resident of Aguada, Puerto Rico. She worked from 2006 - 2008 at De La Salle Catholic at Añasco, Puerto Rico from 2006 – 2008. After exposure to EtO, she was diagnosed with Uterine Cancer in 2007.

85. Plaintiff Idalia Vargas Gratacos is a resident of Villalba, Puerto Rico. Idalia has resided in Villalba since 1983. After exposure to EtO, she was diagnosed with melanoma in 2013 and asthma, high blood pressure, and arthritis in 2003.

86. Plaintiff Juana Castro Moreno is a resident of Fajardo, Puerto Rico. Juana has lived in Fajardo since 1994. After exposure to EtO, Juana was diagnosed with Stage 5 Breast Cancer in 2012.

87. Regrettably, Plaintiffs reside or have resided, frequent or have frequented, work or have worked, and/or attend school or have attended school in census tracks exposed to EtO levels that, according to the U.S. EPA, correspond with a cancer risk of up to 6000 cancer cases per million, which is 600 times higher than the national average cancer risk.

88. Named Plaintiffs, like many other Puerto Rican residents, unknowingly lived with and inhaled Defendants' carcinogenic EtO emissions for years.

89. Until recently, Named Plaintiffs had no reason to know the specific amount of EtO that Defendants were releasing, nor how dangerous these levels of EtO emissions were—including their association with elevated cancer risks—nor, that EtO was being emitted in their communities at all.

90. Plaintiffs reside or have resided, have worked or have attended school or daycare nearby the Sterilizer Defendants facilities in areas that, according to the U.S. EPA in 2022, experienced EtO levels which corresponded with a cancer risk as high as 5,000 cancer cases per million in Anasco, which is 500 times the national average cancer risk; 1,000 cancer cases per million in Fajardo, which is 100 times the national average cancer risk; 6,000 cancer cases per million in Salinas, which is 600 times the national average cancer risk; and 800 cancer cases per million in Anasco, which is 80 times the national average cancer risk.

91. These four facilities in Puerto Rico were all included on a “red flag” list of 23 sites by the EPA—indicia of the far higher risk of toxic EtO exposure to Puerto Rican citizens than the American population at large.

92. Furthermore, these numbers do not reflect the cancer risks in these areas over time.

93. According to the EPA, these risks are models based largely on self-reported emissions data that present a snapshot in time and likely do not accurately capture fugitive emissions data and fail to show the higher risks over the past decades.

94. The EPA estimates the percent of air toxins cancer risk attributable to EtO in these areas to be as high as 95.7%.<sup>18</sup> In the cities where these four PR Sterilization Facilities are located, there are no other industries that use and emit EtO. Therefore, the *only* source of EtO and related cancer risk largely comes from the PR Sterilization Facilities.

95. High numbers of cancer cases are reported in areas surrounding these PR Sterilization Facilities. In 2019, Salinas reported 140 confirmed cases of cancers, among the highest incidence rates in Puerto Rico.<sup>19</sup>

### **CLASS ACTION ALLEGATIONS**

96. **Class Definition:** Plaintiffs, Jeanette Perez Maceira, Jose Luis Mateo Perez, Lilliam M. Ortiz, Danisha M. Ortiz Santiago, Yamel Santiago Rivera, Elba Melendez Figueroa, Lianibel Colon Sanchez, Iris M. Rivera Vargas, Idalia Vargas Gratacos, and Juana Castro Moreno bring this action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of themselves and a Class of similarly situated individuals, defined as follows:

All individuals who have resided, worked or attended daycare and/or school within a four-mile radius of Steri-Tech at Carretera 701 KM 0.7 Salinas Industrial Park; Customed Inc. at Carretera Igualdad Street #7, Fajardo; Edward Lifesciences at Parque Industrial Carr. PR-402 KM, 1.4 N, Anasco; and Medtronic PR Operation Co. at Carretera 151, PR-149 KM 56.3, Villalba, Puerto Rico beginning the date of initial emissions of EtO from each facility.

Excluded from the Class are: (1) any Judge or Magistrate presiding over this action and members of their families; (2) Defendants, Defendants' subsidiaries, parents, successors,

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<sup>18</sup> Union of Concerned Scientists, *UCS Report - Invisible Threat, Inequitable Impact: Communities Impacted by Cancer-Causing Ethylene Oxide Pollution*, UNION OF CONCERNED SCIENTISTS <https://www.ucsusa.org/sites/default/files/2023-02/CommercialSterilizers-MON-FacilitySpreadsheet-2.6.23.xlsx>, (last accessed, February 9, 2024).

<sup>19</sup> Associated Press, *Amid High Levels of Contamination, Puerto Rico Town's Residents Plead for Action*, NBC NEWS, (January 30, 2023, 9:43 AM) <https://www.nbcnews.com/news/latino/contamination-salinas-puerto-rico-residents-demand-action-rcna68143>, (last accessed, February 9, 2024).

predecessors, and any entity in which Defendants or their parents have a controlling interest, and its officers and directors; (3) persons who properly execute and file a timely request for exclusion from the Class; (4) persons whose claims in this matter have been finally adjudicated on the merits or otherwise released; (5) Plaintiffs' counsel and Defendants' counsel; and (6) the legal representatives, successors, and assigns of any such excluded persons.

97. **Numerosity:** The exact number of Class members is unknown and not available to Plaintiffs at this time, but on information and belief, over 40,000 individuals fit within the definition of the Class according to 2010 census data. It is, therefore, clear that the members of the Class are so numerous that individual joinder is impracticable.

98. **Commonality and Predominance:** There are many questions of law and fact common to the claims of Plaintiffs and the putative Class and those questions predominate over any questions that may affect individual members of the Class. Common questions for the Class include, but are not necessarily limited to, the following:

- a. Whether Defendants' conduct was negligent;
- b. Whether Defendants owed a duty of care to Plaintiffs and Class Members;
- c. Whether the duty of care owed to the Class included the duty to prevent their exposure to unsafe, unnecessary, and high levels of EtO emissions;
- d. Whether Defendants breached their duty to the Class by exposing them to high levels of EtO and, thus, increasing their risk of contracting illnesses;
- e. Whether medical monitoring and early diagnostic detection is reasonably necessary to protect the Class; and
- f. Whether Plaintiffs and Class Members are entitled to relief, including through the establishment of a fund to provide for medical monitoring and diagnostic costs.

99. **Typicality:** Plaintiffs' claims are typical of the claims of the other members of the Class in that Plaintiffs and the Class Members sustained damages arising out of Defendants' uniform wrongful conduct.

100. **Adequate Representation:** Plaintiffs will fairly and adequately represent and protect the interests of the Class and have retained counsel competent and experienced in complex litigation and class actions. Plaintiffs also have no interests antagonistic to those of the Class and Defendants have no defenses unique to Plaintiffs. Plaintiffs and their counsel are committed to vigorously prosecuting this action on behalf of the members of the Class and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to the Class.

101. **Superiority:** Class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy, as joinder of all members of the Class is impracticable. Individual litigation would not be preferable to a class action because individual litigation would increase the delay and expense to all parties due to the complex legal and factual controversies presented in this Complaint. By contrast, a class action presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court. Economies of time, effort, and expense will be fostered, and uniformity of decisions will be ensured.

102. Plaintiffs reserve the right to revise the foregoing "Class Allegations" and "Class Definition" based on facts learned through additional investigation and in discovery.

**COUNT I**  
**Negligence**  
**(Individually and Collectively against all Defendants)**

103. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

104. At all times relevant, Defendants owed a duty to Plaintiffs and the Class to exercise reasonable care in the operation of their facilities, including the emission of EtO.

105. Notwithstanding their duty, Defendants breached their duty in one or more of the following ways:

- a. Emitting dangerous volumes of EtO into the air from the PR Sterilization Facilities;
- b. Disregarding safe methods to adequately control EtO emissions from the PR Sterilization Facilities;
- f. Failing to warn or advise those who live, work, or attend school in the community that they were being exposed to EtO;
- g. Failing to adequately record test results of high levels of EtO;
- h. Ignoring test results of high levels of EtO;
- i. Underreporting EtO levels; and
- j. Subjecting those who live and work near their facilities to elevated cancer risks.

106. As a proximate result of Defendants' use and emission of EtO, Plaintiffs and the Class Member have breathed in air contaminated with elevated levels of EtO—amounts that are far higher and more hazardous than acceptable standards, including those set by the U.S. EPA.

107. This exposure makes it significantly more likely that Plaintiffs and Class Members will develop further injuries, including several types of cancer and other illnesses, including but not limited to, blood cancers, breast cancers, tumors, and reproductive issues. This makes periodic diagnostic medical examinations reasonably necessary. Plaintiffs and Class Members have suffered and will suffer economic losses and expenses associated with ongoing medical monitoring.

108. Monitoring and diagnostic procedures exist that make early detection of these latent cancers possible and beneficial—facilitating in treatment that will significantly reduce the development of, and health effects associated with, the related cancers.

109. These monitoring and diagnostic procedures are different than those normally recommended in the absence of exposure to toxic gas such as EtO and are reasonably necessary due to Plaintiffs' and Class Members' significant exposure to EtO.

110. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the related cancers.

111. As a result, Plaintiffs and the Class seek a Court-supervised, Defendant-funded medical monitoring program.

**COUNT II**

**Gross Negligence: Willful and Wanton Misconduct**  
**(Individually and Collectively against all Defendants)**

112. Plaintiffs incorporate the foregoing allegations as if fully set forth herein.

113. At all times relevant, Defendants owed a duty to Plaintiffs and the Class Members to exercise reasonable care in the operation of their facilities, including the emission of EtO.

114. At all times relevant, Defendants owed a duty to refrain from intentional, reckless, malicious, fraudulent, willful, and wanton misconduct and/or conduct which exhibited an indifference and/or conscious disregard to the property, health, safety, and well-being of Plaintiffs and those living and working in the area surrounding the facilities. Defendants intentionally, recklessly, maliciously, and fraudulently caused unsafe EtO to emit from their facilities causing damage to Plaintiffs.

115. Defendants were motivated by financial profit to intentionally, recklessly, maliciously, fraudulently, willfully, and wantonly expose Plaintiffs to EtO by failing to take proper precautions to prevent the emission of unsafe levels of EtO from these facilities.

116. The conduct of each of the Defendants as set forth hereinabove showed intentional, reckless, malicious, and fraudulent misconduct. Accordingly, punitive damages should be imposed against each Defendant to punish and deter each Defendant from repeating or continuing such unlawful conduct.

117. Notwithstanding their duty, Defendants breached their duty in one or more of the following ways:

- a. Emitting dangerous volumes of EtO into the air from its facilities;
- b. Disregarding safe methods to adequately control EtO emissions from their facilities;
- c. Failing to warn or advise those who live, work, or attend school in the community that they were being exposed to EtO;
- d. Failing to adequately record test results of high levels of EtO;
- e. Ignoring test results of high levels of EtO;
- f. Underreporting EtO levels; and
- g. Subjecting those who live and work near their facilities to elevated cancer risks.

118. As a proximate result of Defendants' use and emission of EtO, Plaintiffs and the Class have breathed in air contaminated with elevated levels of EtO—amounts that are far higher and more hazardous than acceptable standards, including those set by the U.S. EPA.

119. This exposure makes it significantly more likely that Plaintiffs and Class Members will develop further injuries, including several types of cancer and other illnesses, including but

not limited to, blood cancers, breast cancers, tumors, and reproductive issues. This makes periodic diagnostic medical examinations reasonably necessary.

120. Monitoring and diagnostic procedures exist that make early detection of these latent cancers possible and beneficial—facilitating in treatment that will significantly reduce the development of, and health effects associated with, the related cancers.

121. These monitoring and diagnostic procedures are different than those normally recommended in the absence of exposure to toxic gas such as EtO and are reasonably necessary due to Plaintiffs' and Class Members' significant exposure to EtO.

122. The available monitoring regime is reasonably necessary according to contemporary scientific principles within the medical community specializing in the diagnosis and treatment of the related cancers.

123. As a result, Plaintiffs and the Class seek a Court-supervised, Defendant-funded medical monitoring program.

**COUNT III**  
**Public Nuisance pursuant to 32 L.P.R.A. §2761**  
**(Individually and Collectively against all Defendants)**

124. Plaintiffs reallege and reaffirm each and every allegation set forth in all of the preceding paragraphs as if fully stated herein.

125. Puerto Rican law provides:

Anything which is injurious to health ... so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the wellbeing of a neighborhood, or to a large number of persons ... constitutes a nuisance and the subject of an action. Such action may be brought by any person, public agency or municipality whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance, and by the judgment the nuisance may be enjoined or abated, as well as damages recovered. 32 L.P.R.A. §2761.

126. Defendants' conduct has caused unreasonable and substantial interference with public health and comfortable enjoyment of life and property, such as by causing EtO to be emitted into the atmosphere.

127. Defendants' conduct was a substantial factor in causing Plaintiffs and other Class Members to have to pay medical costs.

128. By causing the emission of EtO into the atmosphere, Defendants have injuriously affected rights common to the general public, such as the rights of the people to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' conduct has caused substantial annoyance, inconvenience, and injury to the public.

129. The Defendants knew that their acts and/or omissions regarding the release of EtO would have a detrimental effect on the health of the Class.

130. Wherefore, Plaintiffs seek costs for medical monitoring, punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

**COUNT IV**  
**Strict Liability - Design Defect**  
**31 L.P.R.A. § 10807**  
**(Individually and Collectively against all Defendants)**

131. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

132. To the extent that the acts or omissions alleged herein occurred before the effective date of the 2020 Puerto Rico Civil Code, Plaintiffs bring this action forward under the provisions of the 1930 Puerto Rico Civil Code and the Puerto Rico Supreme Court applicable case law.

Article 1802 of the 1930 Puerto Rico Civil Code provides:

A person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done. Concurrent imprudence of the party

aggrieved does not exempt from liability but entails a reduction of the indemnity. 31 L.P.R.A. § 5141, PR ST T. 31 § 5141

133. Defendants' EtO and EtO-containing products were not reasonably safe at the time they left their control because they lacked adequate warnings and/or instructions concerning the dangers and hazards associated with EtO.

134. At the time the Defendants manufactured, distributed, marketed, promoted, and sold EtO and EtO-containing products, they knew their products were not safe and were likely if not certain to cause toxic EtO contamination of lands in Class Members.

135. Despite the Defendants' knowledge, they failed to provide adequate warnings and/or instructions that their EtO and EtO-containing products were toxic, carcinogenic, and would injure the Class Members' health and livelihood.

136. The ETO mixtures and ETO-containing products reached the Plaintiffs' and Class Members' lands without any substantial change in condition from when they left the control of the Defendants.

137. Defendants could have warned of and instructed about these dangers but failed to do so and intentionally concealed information in order to maximize profits for decades.

138. Defendants continued to conceal the dangers of ETOs after they manufactured, distributed, marketed, promoted, and sold ETOs and ETO-containing products.

139. The absence of adequate warnings made the product inherently dangerous.

140. Defendants are strictly liable for all damages to the Class arising out of their failure to provide adequate warnings and instructions regarding their unreasonably dangerous ETOs and ETO-containing products.

141. The Defendants' unreasonably dangerous ETO formulas and ETO-containing products caused the permanent presence of ETO in Plaintiffs and Class Members and injury to the

public interest, including threats to the physical and economic health and well-being of the Plaintiffs and Class Members.

142. Plaintiffs and Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future medical costs as a result of Defendants' unreasonably dangerous ETO formulas and ETO-containing products and the presence of ETOs within the bodies of Plaintiffs and Class Members.

143. The Defendants are strictly liable for all damages arising out of their defectively designed ETO formulas, mixtures, and ETO-containing products.

**COUNT V**  
**Strict Liability - Design Defect**  
**31 L.P.R.A. § 5141**  
**(Individually and Collectively against all Defendants)**

144. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

145. To the extent that the acts or omissions alleged herein occurred before the effective date of the 2020 Puerto Rico Civil Code, Plaintiffs bring this action forward under the provisions of the 1930 Puerto Rico Civil Code and the Puerto Rico Supreme Court applicable case law.

146. Article 1802 of the 1930 Puerto Rico Civil Code provides:

A person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done. Concurrent imprudence of the party aggrieved does not exempt from liability, but entails a reduction of the indemnity. 31 L.P.R.A. § 5141, PR ST T. 31 § 5141.

147. Defendants' EtO mixtures and EtO-containing products as described herein constituted an unreasonably and inherently dangerous design of such products in that they contained EtO, a known toxic substance and carcinogen, at the time they left their control.

148. Defendants' EtO mixtures and EtO-containing products' toxicity, ability to bioaccumulate, inability to be contained, and environmental persistence rendered them defective and unreasonably dangerous at all times.

149. Defendants' ETO mixtures and ETO-containing products were unsafe as designed and failed to perform safely in a manner that resulted in the injuries of Plaintiffs.

150. The risk of danger inherent in the design of the Defendants' ETO mixtures and ETO-containing products drastically outweighed any perceived benefits of the design of such products when such products were put to reasonably foreseeable uses.

151. Alternatively, Defendants knew their ETO mixtures and ETO-containing products were unsafe to an extent beyond that which would be contemplated by an ordinary person.

152. Practical and feasible alternative designs for Defendants' ETO mixtures and ETO containing products capable of reducing Class Members' injuries, damages, and financial losses were commercially available, including mineral oils, silicone fluids, vegetable oils, and nonfluid insulating chemicals, as well as alternative chemical formulations and/or additional chemical processing measures.

153. The ETO mixtures and ETO-containing products reached the Class Members' lands without any substantial change in condition from when they left the control of the Defendants.

154. The Defendants' unreasonably dangerous ETO formulas and ETO-containing products caused the permanent presence of ETO in the bodies of Plaintiffs and Class Members and injury to the public interest, including threats to the physical and economic health and well-being of the Plaintiffs and Class Members.

155. Plaintiffs and Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future medical costs as a result of Defendants' unreasonably

dangerous ETO formulas and ETO-containing products and the presence of ETO within the bodies of Plaintiffs and Class Members.

156. The Defendants are strictly liable for all damages arising out of their defectively designed ETO formulas, mixtures, and ETO-containing products.

**COUNT VI**  
**Strict Liability - Failure to Warn and Instruct**  
**31 L.P.R.A. § 10806**  
**(Individually and Collectively against all Defendants)**

157. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

158. Puerto Rican law provides;

They are liable for the resulting damages, even if they are not at fault or negligent, except when the cause of the damage results from force majeure: (d) the owners or possessors of property that constitutes a nuisance, as defined by law, for damages resulting from such condition; or for the storage of substances that threaten the safety of others; 31 L.P.R.A. § 10806, PRS ST T. 31 § 10806.

159. Defendants' EtO and EtO-containing products were not reasonably safe at the time they left their control because they lacked adequate warnings and/or instructions concerning the dangers and hazards associated with EtO.

160. At the time the Defendants manufactured, distributed, marketed, promoted, sold, and used EtO and EtO-containing products, they knew their products were not safe and were likely if not certain to cause toxic EtO contamination of lands in Plaintiffs' and Class Members' communities.

161. Despite the Defendants' knowledge, they failed to provide adequate warnings and/or instructions that their EtO and EtO-containing products were toxic, carcinogenic, and would injure the Plaintiffs' and Class Members' health and livelihoods.

162. Defendants could have warned of and instructed about these dangers but for decades failed to do so and intentionally concealed information in order to maximize profits.

163. Defendants continued to conceal the dangers of ETOs after they manufactured, distributed, marketed, promoted, sold, and used ETO and ETO-containing products.

164. The Plaintiffs and Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future injuries as a result of medical needs attributable to the Defendants' conduct.

165. Defendants are strictly liable for all damages to the Class arising out of their failure to provide adequate warnings and instructions regarding their unreasonably dangerous ETO and ETO-containing products.

**COUNT VII**  
**Strict Liability - Failure to Warn and Instruct**  
**31 L.P.R.A. § 5141**  
**(Individually and Collectively against all Defendants)**

166. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

167. To the extent that the acts or omissions alleged herein occurred before the effective date of the 2020 Puerto Rico Civil Code, Plaintiffs bring this action forward under the provisions of the 1930 Puerto Rico Civil Code and the Puerto Rico Supreme Court applicable case law.

168. Article 1802 of the 1930 Puerto Rico Civil Code provides:

A person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done. Concurrent imprudence of the party aggrieved does not exempt from liability, but entails a reduction of the indemnity. 31 L.P.R.A. § 5141, PR ST T. 31 § 5141.

169. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

170. Defendants' EtO and EtO-containing products were not reasonably safe at the time they left their control because they lacked adequate warnings and/or instructions concerning the dangers and hazards associated with EtO.

171. At the time the Defendants manufactured, distributed, marketed, promoted, sold, and used EtO and EtO-containing products, they knew their products were not safe and were likely if not certain to cause toxic EtO contamination of lands in Class Members.

172. Despite the Defendants' knowledge, they failed to provide adequate warnings and/or instructions that their EtO and EtO-containing products were toxic, carcinogenic, and would injure the Plaintiffs' and Class Members' health and livelihoods.

173. Defendants could have warned of and instructed about these dangers but failed to do so and intentionally concealed information in order to maximize profits for decades.

174. Defendants continued to conceal the dangers of ETO after they manufactured, distributed, marketed, promoted, sold, and used ETO and ETO-containing products.

175. The absence of adequate warnings made the product inherently dangerous.

176. The Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future, injuries as a result of medical needs attributable to the Defendants' conduct and the absence of adequate warnings or instructions.

177. Defendants are strictly liable for all damages to the Class arising out of their failure to provide adequate warnings and instructions regarding their unreasonably dangerous ETOS and ETO-containing products.

**COUNT VIII**  
**Negligent Design Defect**  
**(Individually and Collectively against all Defendants)**

178. Plaintiffs restate, reallege, and incorporate by reference each of the foregoing paragraphs as if fully set forth herein.

179. The Defendants owed a duty of reasonable care to protect Plaintiffs and Class Members against the unreasonable health and safety risks resulting from the production, use, and disposal of EtO and EtO-containing products at their respective plants.

180. The Defendants failed to exercise ordinary care because a reasonably careful company—that knew of EtO’s toxicity, carcinogenicity, danger to humans, and destruction of the lands—would not manufacture, distribute, use, and dispose of those products; would warn of their toxic and environmentally hazardous properties; or would take steps to enhance the safety and/or reduce the toxicity and environmental persistence of the products.

181. Defendants failed to exercise ordinary care because reasonably careful companies that knew that EtO could not be contained during normal production, distribution, use, and disposal efforts would not continue to manufacture, distribute, use, and attempt to dispose of EtO in a way that allowed the discharge of EtO into and onto Plaintiffs’ and Class Members’ lands.

182. Defendants failed to exercise ordinary care because reasonably careful companies would not continue to manufacture, distribute, use, and dispose of EtO in mass quantities and to the extent and in the applications that Defendants manufactured and attempted to dispose of them.

183. Defendants failed to exercise ordinary care because reasonably careful companies would use basic precautionary measures of adding an odor to EtO that would alert residents in the vicinity of the toxic EtO emissions present in the air they were breathing.

184. Defendants’ EtO and EtO-containing products in Plaintiffs and Class Members caused and continue to cause injury and damage to the health and well-being of Plaintiffs and Class Members.

185. Plaintiffs and Class Members have suffered, are suffering, and will continue to suffer into the indeterminable future injuries as a result of Defendants' failure to warn and instruct.

**COUNT IX**  
**Gross Negligent Design Defect**  
**(Individually and Collectively against all Defendants)**

186. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

187. Defendants knew or should have known of the effects inherently caused by the normal use and operation of their EtO facilities and products, including the likelihood and likely severity of injury to those who live and work in the communities adjacent to facilities which emit EtO.

188. Defendants, collectively and individually, owed a duty to those who live and work in the areas surrounding the EtO facilities to exercise reasonable care in emissions of EtO from entering the area surrounding these facilities and prevent reasonably foreseeable harm that could have resulted therefrom.

189. Defendants knew or should have known that their actions might cause harm and consciously disregarded the foreseeable harm that could have resulted therefrom.

190. Wherefore, Plaintiffs seek punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

**COUNT X**  
**Private Nuisance pursuant to 32 L.P.R.A. §2761**  
**(Individually and Collectively against all Defendants)**

191. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

192. Puerto Rican law provides:

Anything which is injurious to health ... so as to interfere with the comfortable enjoyment of life or property ... constitute a nuisance and the subject of an action. Such action may be brought by any person, public agency or municipality whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance, and by the judgment the nuisance may be enjoined or abated, as well as damages recovered. 32 L.P.R.A. §2761.

193. Defendants' conduct has caused unreasonable and substantial interference with the Plaintiffs and Class Members' lives and comfortable enjoyment of their lives and properties, causing substantial health impacts to the class, costs which have been unreasonably borne by the Plaintiffs and Class Members who suffered, and continue to suffer, losses by having to pay the cost to abate these risks to their health.

194. Defendants' conduct was a substantial factor in causing Plaintiffs and Class Members to have to pay these costs and damages.

195. Wherefore, Plaintiffs and Class Members seek punitive and compensatory damages in excess of \$75,000 from all Defendants, jointly and severally.

**COUNT XI**  
**Restitution – Unjust Enrichment**  
**(Individually and Collectively against all Defendants)**

196. Plaintiffs reallege and reaffirm each and every allegation set forth in all the preceding paragraphs as if fully stated herein.

197. Defendants have avoided liability for these costs.

198. In equity and fairness, it is the Defendants, not the Plaintiffs and Class Members, who should bear the costs of healthcare for the Plaintiffs and Class Members. As a result, the Defendants have been unjustly enriched to the extent that the Plaintiffs and Class Members have had to pay these costs.

199. As a result of the Defendants' acts and omissions specified herein, the Plaintiffs and Class Members were forced to spend far more on actual healthcare costs to identify and remedy their medical needs.

### **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs, Jeanette Perez Maceira, Jose Luis Mateo Perez, Lilliam M. Ortiz, Danisha M. Ortiz Santiago, Yamel Santiago Rivera, Elba Melendez Figueroa, Lianibel Colon Sanchez, Iris M. Rivera Vargas, Idalia Vargas Gratacos, and Juana Castro Moreno, individually and on behalf of the Class, requests that the Court enter judgment in their favor and against Defendants as follows:

- a. An Order certifying the Class as defined herein and appointing Plaintiffs Jeanette Perez Maceira, Jose Luis Mateo Perez, Lilliam M. Ortiz, Danisha M. Ortiz Santiago, Yamel Santiago Rivera, Elba Melendez Figueroa, Lianibel Colon Sanchez, Iris M. Rivera Vargas, Idalia Vargas Gratacos, and Juana Castro Moreno and this Counsel as representatives of the Class;
- b. An award of damages, including nominal and compensatory damages, as allowed by law and in an amount to be determined;
- c. An Order creating a fund for a medical monitoring program in an amount determined to be just and reasonable;
- d. An award of punitive damages as allowed by law and in an amount to be determined;
- e. An award of attorneys' fees, costs and litigation expenses;
- f. An award of prejudgment interest on all amounts awarded;
- g. An Order for injunctive and declaratory relief; and
- h. Such other and further relief as this Court may deem just and proper.

**JURY TRIAL**

**Plaintiffs demand a trial by jury on all issues so triable.**

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Respectfully Submitted: February 28, 2024

/s/ Luis V. Almeida-Olivieri

Luis V. Almeida-Olivieri (PR Bar #308307)

Douglas H. Sanders (PR Bar #302813)

Melissa K. Sims (*pro hac vice forthcoming*)

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